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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,687	08/07/2006	Isabelle Rault	33379-US-PCT	4963

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
04/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/572,687	RAULT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 - 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 - 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed January 22, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17 – 23 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This new matter rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 23, 2009 and those set forth below.

Applicant traverses this rejection by citing the entire specification for support that only contains a single-active tablet and there is no teaching or suggestion that a second active included in said tablet. A positive recitation of that which is inherent in the text is not new matter.

These arguments are unpersuasive. 'Pharmaceutically active substance" is a broad term which encompasses other ingredients which are present in the formulation. Starch breaks down in the body to glucose, which exerts an effect on the body. Lactose, particularly in those individuals who are lactose intolerant, is also pharmaceutically active. Therefore it is not inherent that the compositions described in the specification only contain one pharmaceutically active substance and this limitation is still deemed new matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 17 – 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. (US 6,558,701) in view of De Haan et al. (US 2006/0051420) and the SEPIFILM® product page (accessed 4/10/09). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed April 24, 2009 and September 23, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the scope of the claims has been limited by the use of the transitional phrase "consisting essentially of" and the Examiner's refusal to narrowly interpret the claims absent an indication in the specification or claims is not understood. Attention is directed to the entire specification that describes tablets with a single active ingredient surrounded by a single film coating, which makes clear the basic and novel characteristics of the claimed compositions.

There arguments are unpersuasive. As set forth in greater detail on p 5 – 6 of the September 23, 2009 Office Action indicate that as both the instant claims and the tablets of Bartholoameus et al. are useful for administration to a patient, the inclusion of a second analgesic ingredient does change or materially affect the administration of the

tablet to a patient. The Examiner is following the guidlelines for interpreting this transitional language set forth in MPEP 2111.03 and Applicants have not successfully rebutted these arguments to persuasively argue that the inclusion of tramadol materially affects the administration of the tablet dosage form. It is also noted, as discussed in greater detail above, the other ingredients in the composition such as starch and lactose are pharmaceutically active ingredients which are present in the tablet core.

Applicant also argues that only improper redrafting of the claim can support the statements of the Examiner that removal of the second active ingredient from the compositions of the cited prior art is not required. The numerous side effects which occur with use of tramadol means that is in fact a material effect from the inclusion of this second active is without medical basis.

These arguments are unpersuasive. The interpretation for the transitional phrase is not improper redrafting as it follows MPEP 2113.03. In these context, "material effects" are not necessarily the medical effects of the ingredients on a patient but rather a legal conclusion in which the burden is shifted to Applicant to show that tramadol materially changes the characteristics of the invention (middle of p 6 of the September 23, 2009 Office Action).

Applicant also traverses the Examiner's creative definition of a "separating layer". The meanings of coatings and separating layers were discussed at length in the July 24, 2009 response. Using the logic set forth by the Examiner, an uncoated packaged in a sealed bottle would be prior art because the coating can separate the tablet from the

external environment. Words must be interpreted in light of their ordinary definitions and there is no basis for creative definitions.

This argument is unpersuasive. A bottle surrounding an uncoated tablet would only read on the instant claims if the bottle wall contained 60-70% hydroxypropyl methyl cellulose (HPMC), 8-12% stearic acid, 5-15% microcrystalline cellulose (MCC) and 10-20% titanium dioxide (all percentages w/w). The instant claims also do not use the terminology of "separating layer" and the explanation set forth by the Examiner was used to illustrate that separating layer does not absolutely require the presence of an additional later on a pharmaceutical dosage form such as a tablet, in keeping with the ordinary definition of this term. Applicants have not presented any evidence that the definition set forth by the Examiner is contrary to the ordinary definition of this term.

Applicant also argues that the Examiner has not meet the burden of proof necessary for a rejection under 35 USC 103(a) merely by stating that hardness and compressability are known to one of ordinary skill in the art does not support the rejection. The search for improving these qualities is merely an open invitation to experiment without guidance.

These arguments are unpersuasive. The full discussion of the teachings of the prior art and in the instant claims can be found in April 24, 2009 Office Action, which was incorporated into the September 23, 2009 response. The Examiner assumes the reference about hardness and compressability are made to the April 24, 2009 Office Action in the absence of a citation from Applicant as to the particular statements being argued. The hardness and compressibility are determined by the ingredients and

process by which the tablet is formed. These properties were referenced by the Examiner as parameters which are effected by the amount of the various ingredients which are present in the composition, rendering the amounts of those ingredients results effective parameters that the person of ordinary skill in the art would routinely optimize. The teaching, suggestion or motivation for optimization need not be found in the explicit teachings of the references but can come from the knowledge of one of ordinary skill in the art. Applicants have not presented evidence that the amount of the ingredients do not affect the hardness or compressibility of the tablet mixture or other evidence that the amounts of these ingredients are not results effective parameters that would be routinely optimized.

Applicant also argues that it is not relevant to the present situation that the presentation in the prior art of more than one alternative is not a teaching away. The dosage form of US'420 teaches delaying the degradation of the active compound by using a "wrap" coating that can be a film, but is preferably a sugar or sugar film coating. Not all of the film materials have the desired stabilizing effect. Selection without undue experimentation from the genus of films when it is known that not all film materials have the desired stabilizing effect means that the artisans of ordinary skill would prefer not to use any of the less desirable films and would prefer to use a sugar or sugar film coating. Thus, the reference teaches away from the coating of the present invention and there is no reasonable expectation of success. SEPTIFILM [sic] adds nothing to the Examiner's arguments as it only teaches that certain films are known in the art.

These arguments are unpersuasive. The artisan of ordinary skill would not expect that all possible film materials would be suitable for all applications. De Haan states that EUDRAGIT® E PO and EUDRAGIT® L100 should not be used to coat tibilone tablets as these coatings do not have the desired stabilizing effect (¶ [0013]). This is not a criticism, discreditation or otherwise discouraging the use of these films to coat tablets with other active ingredients. Different active ingredients will have different mechanisms of degradation so those exemplified may be suitable for other active ingredient tablets. There is no teaching away from non-sugar film materials as preferred embodiments do not constitute a teaching away (p 8 of September 23, 2009 Office action for a fuller discussion). Only a reasonable expectation success, a not an absolute expectation of success, is required to establish a *prima facie* case of obviousness. That level exists based on the teaching of the prior art that a wide variety of film coating materials, only some of which will not work in conjunction with a specific active ingredient, and the teachings the SEPIFILM® generically lowers moisture permeability and improves moisture resistance for dosage forms.

8. Claims 17 – 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al., De Haan et al. and SEPIFILM® product page further in view of Gimet et al. (US 5,601,843). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed April 24, 2009 and September 23, 2009 and those set forth below.

Applicant traverses this rejection on the addtional ground that the relevance of US'843 to the present invention is remote and adds nothing to the Examiner's arguments. The dosage form of US'843 has a core with an NSAID and a coating with a prostaglandin which may be separate by an intermediate coating, *contra* to the instant claims which contain a single active in the core and no active in the coating. The core of the tablet in US'842 is covered by up to 4 coatings - enteric, aqueous enteric, overcoat and mantle, each with a different composition and purpose. No one of them suggests the single film coating of the instant invention. This combination of references does not make obvious the instant claims.

These arguments are unpersuasive. The arguments regarding Bartholomaeus et al., De Haan et al. and SEPIFILM® were discussed above. Gimet et al. is relevant as set forth on p 9 of the September 23, 2009 Office Action, for the explicit teaching of a core containing 2-15% by weight of microcrystalline cellulose and not the layer structure of the dosage form. The interpretation of the transitional phrase of the claims, allowing for the inclusion of additional layers, was discussed in greater detail above and is also used for this rejection. Applicants have not argued why the teachings of Gimet et al. as to suitable amounts of MCC in the core of tablets containing an active ingredient is not applicable to the instant claims. Therefore, this rejection is maintained.

9. Claims 17 – 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al., De Haan et al. and SEPIFILM® product page further in view of Humbert-Droz et al. (US 6,083,531). This rejection is MAINTAINED for the reasons of

record set forth in the Office Actions mailed April 24, 2009 and September 23, 2009 and those set forth below.

Applicant traverses this rejection on the additional ground that the relevance of US'531 is remote and adds nothing to the Examiner's arguments. The lack of coating of the tablet is understandable as the purpose of the composition is to be fast dissolving in the mouth. This combination of references does not make obvious the instant claims.

These arguments are unpersuasive. The arguments regarding Bartholomaeus et al., De Haan et al. and SEPIFILM® were discussed above. Humbert-Droz et al. was cited for its teaching of a 12.5 mg dosage of diclofenac potassium per unit dose, relevant to the diclofenac containing dosage forms of Bartholomaeus et al. and the instant claims. Applicants have not argued why the teachings of Humbert-Droz et al. as to diclofenac dosages is not applicable to the instant claims. Therefore, this rejection is maintained.

10. Claim 24 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gimet et al. (US 5,601,843) in view of Humbert-Droz et al. (US 6,083,531), Voss et al. (US 5,690,927), De Haan et al. (US 2006/0051420) and the SEPIFILM® product page (accessed 4/10/09). This rejection is MAINTAINED for the reasons set forth in the Office Action mailed Sept 23, 2009 and those set forth below.

Applicants traverse this rejection on the grounds that Voss teaches a tablet containing codeine, an active with many undesirable side effects. To say that there is no material effect from the inclusion of this second active ingredient – as the Examiner

must do in order to support this rejection – is without medical basis. In addition to the arguments already set forth regarding these references singly or in combination, it is suggested that as the Examiner must use 5 references to attempt to craft an obviousness rejection, the she has merely picked bits and pieces in hindsight.

These arguments are unpersuasive. As discussed in greater detail, Applicants have not met the burden to establish that codeine is excluded from the instant claims and the same interpretation of "consisting essentially of" as described of in regards to claim 17 above. A core containing diclofenac alone is taught by Gimet et al. – the prostaglandins of the dosage forms of Gimet et al. is contained in the coating, so Voss et al. is not the only reference that contains relevant teachings regarding the composition of the core of the tablet formation.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). Applicants have not provided additional reasoning to weigh against the obviousness of the claimed invention. Due to the number of specific ingredients and amounts of those ingredients set forth in claim 24, a number of references are required to teach or suggest all of the limitations of the claim.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicants have not rebutted the reasoning set forth on p 12 – 14 of the September 23, 2009 Office Action so this rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW